



DECLARATION UNDER 37 C.F.R. § 1.132

I, Claus Christiansen, declare as follows:

I am a Danish citizen, and I presently reside at Casa Sirenella, 6922 Morcote, Switzerland. I am an expert in the field of endocrinology, which relates to the subject matter of U.S. Patent Application Serial No. 10/561,639, the patentability of which is presently at issue.

My present position is a board member and major shareholder of Rheoscience A/S, Glerupvej 2, 2610 Roedovre, Denmark. I have been working with Rheoscience A/S for approximately 5 years.

My education includes training in medical school and Ph D in medical sciences.

I have read and understood US Patent Application No. 10/561,639 (which I understand was published as US 2007/0010423) and I am familiar with the amended claims currently under consideration.

I have reviewed the test results attached to this declaration, as Annex I, relating to the administration of balaglitazone, a DPP-IV inhibitor (LAF-237), and the combination of the two to Zucker Diabetic Fatty (ZDF) rats for a period of 42 days.

Based upon each test, the following results were obtained. ZDF rats that were treated with only balaglitazone showed an increase in body weight, increased insulin secretion, and reduced Hemoglobin A1c (HbA1c). ZDF rats that were treated with only a DPP-IV inhibitor (LAF-237) showed a decrease in fasting plasma glucose, a reduced HbA1c, and increased plasma glucagon-like peptide 1 (GLP-1).

ZDF rats that were treated with the combination of balaglitazone and a DPP-IV inhibitor (LAF-237) showed an increase in body weight, an increase in fasting plasma insulin, an increase in plasma GLP-1, a reduction of HbA1c, a reduction in fasting plasma triglyceride levels, and a reduction in fasting plasma free fatty acid levels.

Based on the results obtained, I am of the opinion that the combination of balaglitazone and a DPP-IV inhibitor (LAF-237) reveals a lowering effect of plasma lipids that was unpredictable based on results from monotherapy. One could not have predicted that the combination of balaglitazone and a DPP-IV inhibitor was much more effective than either composition alone.

I declare that all statements herein made of my own knowledge are true and that all statements made herein on information and belief are believed to be true. I do hereby state that I am aware that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. § 1001) and may jeopardize the validity of the application or any patent issuing thereon.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on: 30 Dec. 2008 (date)

Signature: 